



Refer to the device directions for use for complete instructions on device use.

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Intended Use/ Indications For Use

The EXALT Monitor is intended for use with a Boston Scientific single-use endoscope for endoscopic diagnosis, treatment, and video observations.

Contraindications

None known

Warnings

- Do not use with High Frequency ancillary devices.
- EXALT Monitor images must not be used as an independent diagnostic of any pathology. Physicians must interpret and substantiate any finding by other means and in the light of the patient's clinical characteristics
- The EXALT Monitor is not to be used in a MRI environment.
- Do not use the EXALT Monitor in the presence of flammable fluids and gases such as alcohol or oxygen. Doing so can result in fire and burns to the operator and patient.
- Placing the EXALT Monitor where other electrical medical devices can degrade the video image can delay the procedure and result in adverse events. In addition, placing the EXALT Monitor where it can degrade the performance of other equipment in the endoscopy suite due to EMI emissions can delay the procedure or result in adverse events. Verify operation in the endoscopy suite environment before starting a procedure. Follow ancillary equipment instructions for use to locate ancillary equipment. Using the EXALT Monitor without cleaning the exterior surfaces including touch screen user interface can expose the operator to biohazardous materials. To prevent exposure to biohazardous materials, clean the device between uses.
- If the EXALT Monitor is connected to an improperly grounded power supply, electrical leakage can result in electrical shock to the user. To avoid risk of electrical shock, this equipment must only be connected to a supply mains with protective earth.
- Do not touch connecting devices for electrical connections between the different components (such as signal input and output connections for video signals, data exchange, control circuits, etc.) and the patient at the same time. Doing so can result in electric shock to the patient.
- The use of accessories and cables other than those specified or supplied as spare parts from Boston Scientific may result in increased emissions or decreased immunity of the EXALT Monitor or single-use endoscope.
- Components connected to the EXALT Monitor by the user must be certified to the respective IEC standards (IEC 60601-1 for medical equipment, IEC 60950 for data processing equipment, and IEC 60065 for A/V equipment). In addition, the user must ensure the new configuration complies with the IEC 60601-1 standard.



Precautions

- Connecting an incompatible single-use endoscope to the EXALT Monitor can damage the EXALT Monitor.
- Locate the EXALT Monitor appropriately to avoid accidentally pulling cable connections, which can result in disconnection and loss of visualization.
- Before starting a procedure, ensure components such as the secondary video monitor and irrigation pump that support the EXALT Monitor and single-use endoscope are present and operational. Starting a procedure without the supporting components present and operational can prolong the procedure.
- Do not use cleaning solutions that contain long-life surfactants. Doing so can leave conductive residues on the contacts of the single-use endoscope connector receptacle. The conductive residues can lead to malfunctions of the EXALT Monitor.
- Applied parts of other electrical medical equipment in application with this equipment have to be type BF.

Adverse Events

- Please refer to single-use endoscope instructions for use.